

### **REMARKS**

Claims 20-31, 33, 34, 36-42, 44-49, 51, 52, 54-63, 65, 66, 68-70, 73, 74, 76 and 77 remain in this application. Claims 32, 35, 43, 50, 53, 64, 67, 71, 72 and 75 have been cancelled. Claims 78-85 have been added.

Basis for the amendments is as follows:

Claim 20 has been amended to incorporate the limitations of claims 32 and 35.

Claim 42 has been amended to incorporate the limitations of claims 50 and 53.

Claim 60 has been amended to incorporate the limitations of claims 64 and 67.

Claim 70 has been amended to incorporate the limitations of claims 72 and 75.

New claims 78-85 find basis on page 15, lines 17-18 which state “preferably negative going if monophasic, preferably negative/positive if biphasic...”

#### **Objection under 35 U.S.C. 175(c)**

In the Office Action, the Examiner objected to claims 43 and 71 under 35 U.S.C. 175(c) as being in improper dependent form for failing to further limit the subject matter of a previous claim.

Claims 43 and 71 have been cancelled thus mooted this rejection.

#### **Rejection under 35 U.S.C. 102(a)**

Claims 20-21, 27-28, 30, 38, 42-43, 47, 56, 60-61 and 63 stand rejected under 35 U.S.C. 102(a) as being anticipated by Riso (“Strategies for providing upper extremity amputees with tactile and hand position feedback” in Technology and Health Care, Fall 1999). The above

claims as amended are believed to distinguish the present invention over the cited references for the following reason.

Amended claim 20 recites:

“A system for alleviating phantom limb pain and selectively delivering stimulation signals to a patient having a limb stump, comprising:

a prosthetic limb that is attachable to the patient's limb stump, the prosthetic limb including a plurality of sensors that produce sensory signals;

a signal generator for producing electrical stimulation signals to stimulate one or more selected sensory nerve fibers of a severed limb nerve, the electrical stimulation signals being in the form of impulses having a duration in the range of about 10 to 1000 $\mu$ s and a current amplitude selected to be 1-10 times a current threshold required to recruit a large diameter sensory nerve fiber without recruiting a pain nerve fiber, and approximating a pattern of sensations that would be received from a normal, innervated limb before it was amputated;

a microprocessor that receives the sensory signals and is programmed to cause the signal generator to produce the electrical stimulation signals and to deliver the electrical stimulation signals to the one or more selected sensory nerve fibers in order to provide sensations to the patient that appear to arrive from the prosthetic limb, wherein the selection of the one or more sensory nerve fibers is based on feedback from the patient regarding which sensory nerve fibers correspond to which of the plurality of sensors;

means for transmitting the sensory signals from the plurality of sensors to the microprocessor; and

means for transmitting the electrical stimulation signals to the selected sensory nerve fibers;

wherein the means for transmitting the electrical stimulation signals to the selected sensory nerve fibers includes a plurality of electrodes adapted for implantation in close proximity to the severed limb nerve and wherein each electrode is in close proximity to different sensory nerve fibers of the severed limb nerve.” [Emphasis added]

Applicant submits that Riso does not disclose the electrical stimulation signals being in the form of impulses having a duration in the range of about 10 to 1000 $\mu$ s nor a current amplitude selected to be 1-10 times a current threshold required to recruit a large diameter sensory nerve fiber without recruiting a pain nerve fiber. In the Office Action, the Examiner contends that “varying stimulation parameters in order to determine the most optimal configuration is well known in the art.”, Applicant disagrees and suggests the following reasons for disagreeing. Although it could appear to be obvious to adjust the given parameters in order to obtain the determine the most optimal configuration, it is not readily apparent which parameters should be adjusted and, once the parameters to be adjusted are chosen, such adjustment can become tedious and time consuming when no guidelines are available. It has been discovered that, to reach the desired result of producing electrical stimulation signals approximating a pattern of sensations that would be received from a normal, innervated limb before it was amputated, that electrical stimulation signals in the form of impulses having a duration in the range of about 10 to 1000 $\mu$ s and a current amplitude selected to be 1-10 times a current threshold required to recruit a large diameter sensory nerve fiber without recruiting a pain nerve fiber can be advantageously used, as taught in amended Claim 20. It is submitted that neither the nature of the parameters to be adjusted and the ranges of adjustments of such parameters are mentioned or suggested in the Riso. Also, selecting these particular parameters as well as their adjustment ranges are believed to involve inventive ingenuity over Riso; one has to further investigate to find the nature of the parameters as well as their adjustment ranges since these data are not readily available from Riso.

The Applicant therefore submits that amended claim 20 is not anticipated by Riso. Furthermore, as claims 21, 27-28, 30, 38 and 78-79 directly or indirectly depend on an allowed base claim, these claims should also be allowable.

Claims 60-64, 65-66, 68-69 and 80-81 are method claims and corresponding to allowable claims 20-21, 27-28, 30 and 38. For this reason, it is believed that these claims should not be considered as anticipated in view of Riso.

Amended claim 42 recites:

“A system for alleviating phantom limb pain of a patient having a limb stump, comprising:

a signal generator for producing electrical stimulation signals to stimulate one or more selected sensory nerve fibers of a severed limb nerve, the electrical stimulation signals being in the form of impulses having a duration in the range of about 10 to 1000 $\mu$ s and a current amplitude selected to be 1-10 times a current threshold required to recruit a large diameter sensory nerve fiber without recruiting a pain nerve fiber, and approximating a pattern of sensations that would be received from a normal, innervated limb before it was amputated;

a microprocessor that is programmed to cause the signal generator to produce the electrical stimulation signals and to deliver the electrical stimulation signals to one or more selected sensory nerve fibers in order to alleviate phantom limb pain, wherein the selection of the electrical stimulation signals is based on feedback from the patient; and

means for transmitting the electrical stimulation signals to the selected sensory nerve fibers;

wherein the means for transmitting the electrical stimulation signals to the selected sensory nerve fibers includes a plurality of electrodes adapted for implantation in close

proximity to the severed limb nerve and wherein each electrode is in close proximity to different sensory nerve fibers of the severed limb nerve.” [Emphasis added]

The Applicant respectfully reiterates the arguments of amended claim 20 and submits that claim 42 is not anticipated by Riso. Furthermore, Applicant submits that dependent claims 44-49, 51-52, 54-59 and 82-83 are directly or indirectly dependent on allowable claim 42. These claims are also considered not to be anticipated by Riso.

Likewise, method claims 70, 73-74, 76-77 and 84-85 which are dependent claims corresponding to allowable claims 42, 44-49, 51-52, 54-59 are not considered to be anticipated by Riso.

#### **Rejection under 35 U.S.C. 103(a)**

Claims 23-26, 29, 31-37, 41, 44-46, 48-55, 59 and 64-69 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Riso (“Strategies for providing upper extremity amputees with tactile and hand position feedback” in Technology and Health Care, Fall 1999). The above claims as amended are believed to distinguish the present invention over the cited references for the following reason.

The Applicant respectfully reiterates the arguments of amended claim 20 in support of the patentability of these claims and further submits that claims 23-26, 29, 31-37, 41, 44-46, 48-55, 59 and 64-69 as being dependent either directly or indirectly on allowable claims 20, 42, 60 or 70 are also patentable over Riso.

Claims 22, 62 and 70-77 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Riso (“Strategies for providing upper extremity amputees with tactile and hand position feedback” in Technology and Health Care, Fall 1999) in view of U.S. Patent No. 4,232,679 (“Schulman”). These claims as amended are believed to distinguish the present invention over the cited references for the following reason.

Applicant submits that Schulman does not disclose the electrical stimulation signals being in the form of impulses having a duration in the range of about 10 to 1000 $\mu$ s nor a current amplitude selected to be 1-10 times a current threshold required to recruit a large diameter sensory nerve fiber without recruiting a pain nerve fiber. The Applicant also respectfully reiterates the arguments of amended claim 20.

Applicant submits that claim 70 is patentable over Riso in view of Schulman. Also, as claims 22, 62 and 72-77 are either directly or indirectly dependent on one of corresponding allowed base claims, that these claims are also patentable over Riso in view of Schulman.

Claims 39-40 and 57-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Riso ("Strategies for providing upper extremity amputees with tactile and hand position feedback" in Technology and Health Care, Fall 1999) in view of U.S. Patent No. 5,824,027 ("Chen"). The above amended claims are believed to distinguish the present invention over the cited references for the following reason.

Applicant submits that Chen does not disclose the electrical stimulation signals being in the form of impulses having a duration in the range of about 10 to 1000 $\mu$ s nor a current amplitude selected to be 1-10 times a current threshold required to recruit a large diameter sensory nerve fiber without recruiting a pain nerve fiber. Applicant again respectfully reiterates the arguments of amended claim 20.

It is submitted that claims 39-40 and 57-58 either directly or indirectly depend on allowable claims 20 or 42 and are therefore also patentable over Riso in view of Chen.

Claims 60-61 and 63-69 are further rejected under 35 U.S.C. 103(a) as being unpatentable over Riso ("Strategies for providing upper extremity amputees with tactile and hand position feedback" in Technology and Health Care, Fall 1999) in view of U.S. Patent No. 5,314,495 ("Kovacs"). The amended claims are believed to distinguish the present invention over the cited references for the following reason.

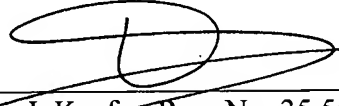
Applicant submits that Kovacs does not disclose the electrical stimulation signals being in the form of impulses having a duration in the range of about 10 to 1000 $\mu$ s nor a current amplitude selected to be 1-10 times a current threshold required to recruit a large diameter sensory nerve fiber without recruiting a pain nerve fiber. Applicant again reiterates the arguments of amended claim 20.

It is therefore submitted that claim 60 is patentable in view of this rejection. Furthermore, Applicant submits that claims 61 and 63-69 which are either directly or indirectly dependent on allowable claim 60 are also patentable over Riso in view of Kovacs for at least these reasons.

Applicants respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully Submitted,

Date: 9/13/06

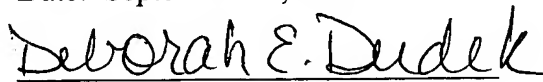
  
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